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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,741	07/31/2001	Chad J. Roy	920070.405	3947

30465 7590 07/15/2003

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EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 07/15/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/919,741

Applicant(s)

ROY ET AL.

Examiner

Robert L. Nasser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 23,24,27,32-34,36,44-46 and 66-133 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 23,27,35,39,68-73,80,81,83,86,102-107,114,115,117 and 120 is/are rejected.
- 7) ☐ Claim(s) 24, 32-34, 36, 44-46, 66, 67, 74-79, 82, 84, 85, 87-101, 108-113, 116, 118, 119, 121-133 is/are objected

to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23, 27, 35, 39, 68, 69, 71, 72, 80, 84, 102, 103, 105, 106, 114, and 117 are rejected under 35 U.S.C. 102(\*b) as being anticipated by Frankel et al. Frankel shows a n inhalation chamber for supplying a aerosol vaccine to a bird, which has the step of automatically controlling the humidity and temperature of the chamber, which are clear part of the environment, and automatically controlling the feed rate and droplet size of the aerosol, which clearly controls the concentration in the chamber. The examiner notes that the humidity and temperature are kept constant by providing feedback from humidity and temperature sensors. The examiner notes that Frankel discloses that the temperature is controlled on column 2, line 55. As such, it is inherent that there be a sensor to feedback to temperature to enable control. In addition, the aerosol is a wet aerosol, or mist. The examiner notes that Frankel also teaches the claimed apparatus, noting that the means for controlling the environment are a sensor providing feedback to a controller, which is equivalent to the disclosed structure. In

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addition, it is the examiner's position that the means to control droplet size and feed rate is equivalent to the disclosed structure to control the dosage.

Claims 23, 25, 35, 39, 68, 69, 71, 72, 80, 81, 83, 86, 102, 103, 105, 106, 114, 115, 117, and 120 are rejected under 35 U.S.C. 102(e) as being anticipated by Schuster et al. Schuster shows a method including the steps of controlling the environment of an inhalation chamber in an inhaler (i.e. controlling the temperature and humidity) and also the step of controlling the dose concentration. The humidity and temperature are controlled via sensors which feedback information to a controller. The drug can be a wet or dry aerosol in a carrier or airborne. The examiner notes that in applicant's specification, the inhalation chamber is one where an animal is at least partially inside the chamber. However, nothing on the record limits the definition of inhalation chamber to this type of chamber and the chamber in an inhaler is called an inhalation chamber. If applicant were to amend the claims to define the chamber as disclosed in the specification, it would overcome the art of record. For example, applicant might recite that the chamber has openings to allow a portion of an animal to extend into the chamber.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 70, 73, 104, and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frankel et al. The examiner takes official notice that PID sensors for

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temperature and humidity are well known. Hence, it would have been obvious to modify Frankel to use PID sensors, as it is merely the substitution of one known equivalent sensor for another.

Claims 70, 73, 104, and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schuster et al. The examiner takes official notice that PID sensors for temperature and humidity are well known. Hence, it would have been obvious to modify Schuster et al to use PID sensors, as it is merely the substitution of one known equivalent sensor for another.

Claims 24, 32-34, 36, 44-46, 66, 67, 74-79, 82, 84, 85, 87-101, 108-113, 116, 118, 119, and 121-133 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's arguments filed 4/23/2003 have been fully considered but they are deemed moot in view of the new grounds of rejection.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lloyd et al and Raghuprasad show inhalers that control the dose or environment.

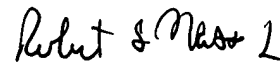
Rothenberg et al and Cannon et al show metered dose inhalation chambers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on MAXIFLEX.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Robert L. Nasser  
Primary Examiner  
Art Unit 3736

RLN  
July 14, 2003

**ROBERT L. NASSER**  
**PRIMARY EXAMINER**